

OHRP/FDA/VA

Town Meeting

Evolving Concern for Protection of Human Subjects

Baylor Research Institute

An Affiliate of the Baylor Health Care System

**Monday, December 11, 2000
8:00 AM - 3:30 PM**

OHRP/FDA/VA TOWN MEETING

Office for Human Research Protections
Food and Drug Administration
Department of Veterans Affairs

“Evolving Concern for Protection of Human Subjects”

Monday, December 11, 2000
8:00 AM - 3:30 PM
Davis Auditorium
17th Floor, Roberts Hospital
Baylor University Medical Center
3500 Gaston Ave.
Dallas, TX 75246

**Sponsored by A. Webb Roberts Center for Continuing Education of Baylor Health Care
System, Dallas**

The purpose of this Town Meeting is to ANSWER YOUR QUESTIONS!

Target Audience: Anyone involved in the conduct, sponsorship or oversight of research involving human subjects. This would include Institutional Review Board (IRB) members, chairs and administrators, investigators, study coordinators, students and institutional officials.

Purpose: To enable participants to interpret federal guidelines for protection of human research subjects through direct question-and-answer sessions with colleagues and representatives from federal agencies.

Registration Fee: \$25.00 - includes continental breakfast, breaks and conference materials.

Participant Questions: To provide clarification of all major questions and issues, please forward 3 questions to Ms. Ross at OHRP by Dec 5:
Fax 301/402-0527 email: dr20a@nih.gov

Agenda

- 8:00 a.m.** Registration and Continental Breakfast
- 8:30 a.m.** **Welcome and Introductions**
Michael Ramsay, M.D.
President, Baylor Research Institute
Greg Koski, M.D., Ph.D.
Director, Office of Human Research Protections
- 9:00 a.m.** **Open Panel Discussion: Federal Update**
OHRP – Greg Koski, M.D., Ph.D.
VA – John H. Mather, M.D.
Joan Porter, Ph.D.
FDA – David A. Lepay, M.D., Ph.D.
Questions and Answers
- 10:00 a.m.** Refreshment Break
- 10:15 a.m.** **Open Panel: Current and Emerging Issues**
Research exemptions, expedited reviews, waivers of consent; Subject recruitment and advertising
What constitutes adequate education for IRB members? For investigators?
Data and safety monitoring boards - DSMBs
Adverse event reporting; Avoiding non-compliance
Questions and Answers
- 12:00 p.m.** Lunch on your own
- 1:00 p.m.** **Open Panel: Current and Emerging Issues**
Tissue banking and biological repositories
Genetics research; Psychiatric research
Use of placebos
Information databases and medical records research
Certificates and confidentiality
Special protections for vulnerable populations
Questions and Answers
- 3:30 p.m.** Evaluation and Adjourn

Americans with Disabilities Act:

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Conference Faculty

Greg Koski, M.D., Ph.D.

Director
Office for Human Research Protections

Jeffrey M. Cohen, Ph.D.

Director
Division of Education and Development
Office for Human Research Protections

David A. Lepay, M.D., Ph.D.

Acting Senior Advisor for Clinical Science and
Acting Director, Office of Clinical Science
Office of the Commissioner
U.S. Food and Drug Administration

John H. Mather, M.D.

Chief Officer
Office of Research Compliance and Assurance
Veterans Health Administration
Department of Veterans Affairs

Joan Porter, D.P.A., M.P.H.

Associate Director
Office of Research Compliance and Assurance
Veterans Health Administration
Department of Veterans Affairs

Credit:

A. Webb Roberts Center for Continuing Education of Baylor Health Care System, Dallas designates this educational activity for up to 5.5 hours in Category 1 credit toward the AMA Physician's Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

A. Webb Roberts Center for Continuing Education of Baylor Health Care System, Dallas is accredited by the Accreditation Council for Continuing Medical Education to provide continuing education for physicians.

**Registration Form
Subjects**

Evolving Concern for Protection of Human

**Davis Auditorium, Dallas, TX
Monday, December 11, 2000**

The DEADLINE for registering is December 7, 2000.

Name: _____
Social Sec. No: _____
Mailing Address: _____
City: _____ State: _____ Zip Code: _____
Business Phone: ____/____ Fax No: ____/____
Highest Degree: _____ Email Address: _____
Employer: _____ Specialty/Profession: _____

Registration

You may register by:

- Mailing your check and completed registration form to:
A. Webb Roberts Center, 3500 Gaston,
Dallas, TX 75246
- Faxing your completed registration form with your MasterCard or Visa information to 214/820-4169.
- Telephoning your registration and MasterCard or Visa information to 214/820-2317.

Registration Fee
\$25.00

Method of Payment

☐ Check made payable to A. Webb Roberts Center.

☐ Charge to:

_____ VISA _____ MasterCard

Credit Card No:

Expiration Date: _____

Signature of Cardholder:
